Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Jun 2026

The Effect of High dose of Allopurinol loading on Percutaneous Coronary Intervention Outcomes and In-hospital Clinical Results in ST-segment Elevation Myocardial Infarction Patients; A Double-blind Randomized Clinical Trial

Protocol summary

Study aim

- To determine and compare coronary blood flow after high dose allopurinol loading in ST elevation myocardial infarction patients undergoing primary precancerous coronary intervention

Design

Two arm randomized parallel groups, double blind with control group

Settings and conduct

80 STEMI patients that candidate for primary or rescue PCI are selected according to the inclusion criteria and randomized to two equal groups by computerized method. In the case group, 600 mg of Allopurinol received before the intervention and the control group received placebo medication. After PCI, its results interpreted based on TIMI flow and MBG. Patients were also followed up during hospitalization for MACE and complications. intervening / interpreter and analyzer are blinded.

Participants/Inclusion and exclusion criteria

Entry: Acute STEMI below 24 hours for primary or rescue PCI No entry: Routine PCI, STEMI over 24 hours, Previous consumption of Allopurinol or other anti-inflammatory drugs, Cardiac shock, Pulmonary edema with NYHA class 3/4, Any electrical and mechanical complications of STEMI

Intervention groups

Case group: 600 mg oral dose of Allopurinol before the intervention and immediately after arrival to emergency ward Control group: placebo similar in shape and size with intervention group medication

Main outcome variables

Prescribing a loading dose of Allopurinol before the PCI can be used clinically and practically to achieve better PCI results in STEMI patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181228042155N1**
Registration date: **2019-07-13, 1398/04/22**
Registration timing: **registered_while_recruiting**

Last update: **2019-07-13, 1398/04/22**
Update count: **0**

Registration date

2019-07-13, 1398/04/22

Registrant information

Name

Mohammad Kermani-Alghoraishi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3345 9614

Email address

sm.kermani@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The Effect of High dose of Allopurinol loading on Percutaneous Coronary Intervention Outcomes and In-hospital Clinical Results in ST-segment Elevation Myocardial Infarction Patients; A Double-blind Randomized Clinical Trial

Public title
The Effect of Allopurinol on Percutaneous Coronary Intervention Outcomes in ST-segment Elevation Myocardial Infarction Patients

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Acute ST-segment elevation MI Symptom onset below 24 hours PCI as primary or rescue approach

Exclusion criteria:
Acute STEMI onset more than 24 hours Candide for routine PCI Previous consumption pf Allopurinol and other anti-inflammatory medications Cardiac shock Pulmonary edema with NYHA class 3/4 Mechanical complications of acute STEMI Electrical complication of acute STEMI

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done in simple way by computer. In fact, each patient's code is divided into a group at the beginning of the emergency ward by the computer.

Blinding (investigator's opinion)
Double blinded

Blinding description
- The physician conducting the intervention and interpreting the results of the PCI as well as the patient who follow-up patients during the hospitalization period are blind to the case and control groups. - The data analyzer is also blind to the groups.

Placebo
Used

Assignment
Parallel

Other design features
The first study to examine the effect of pre-intervention Allopurinol administration on PCI results in STEMI patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hezar Jerib St, Isfahan University of Medical Sciences

City
Isfahan

Province
Isfehan

Postal code
81746-73461

Approval date
2019-06-16, 1398/03/26

Ethics committee reference number
IR.MUI.MED.REC.1398.138

Health conditions studied

1

Description of health condition studied
Precancerous Coronary Intervention Outcome

ICD-10 code
I21

ICD-10 code description
ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description
Coronary flow according to Thrombolysis In Myocardial Infarction (TIMI flow)

Timepoint
After precancerous coronary intervention

Method of measurement
Angioplasty videos interpretation

2

Description
Coronary flow according to Myocardial blush grade (MBG)

Timepoint
After precancerous coronary intervention

Method of measurement
Angioplasty videos interpretation

Secondary outcomes

1

Description
Post MI Electrical and Mechanical complication
Timepoint
During hospitalization
Method of measurement
Electrocardiography and Echocardiography

2

Description
Major Adverse Cardiac Events (MACE)
Timepoint
During hospitalization
Method of measurement
Questionnaire and physician interpretation

3

Description
Troponin level
Timepoint
Admission time and 48 hour after it
Method of measurement
Laboratory kit

4

Description
ECG changes
Timepoint
Admission time and after precancerous coronary intervention
Method of measurement
Objective interpretation

Intervention groups

1

Description
Intervention group: Received 600 mg Allopurinol loading before precancerous coronary intervention followed by 100 mg daily up to admission, Jalinous pharmaceutical Co.
Category
Treatment - Drugs

2

Description
Control group: Placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Chamran Heart Center
Full name of responsible person
Mohammad Kermani-Alghoraishi
Street address
Salman Farsi St., Shahid Chamran Heart Center
City
Isfahan
Province
Isfehan
Postal code
۸۱۵۸۳۸۸۹۹۴
Phone
+98 31 3260 0961
Fax
+98 31 3261 1405
Email
sm.kermani@med.mui.ac.ir
Web page address
https://chamran.mui.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr Shaghayegh Haghjooy Javanmard
Street address
Hezar Jerib St., Isfahan University of Medical Sciences
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
sm.kermani@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Kermani-Alghoraishi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Cardiology
Street address
Salman Farsi St., Shahid Chamran Heart Center
City
Isfahan
Province
Isfehan
Postal code
۸۱۵۸۳۸۸۹۹۴
Phone
+98 31 3260 0961
Email
sm.kermani@med.mui.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Kermani-Alghoraishi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Cardiology
Street address
Salman Farsi St., Shahid Chamran Heart Center
City
Isfahan
Province
Isfehan
Postal code
۸۱۵۸۳۸۸۹۹۴
Phone
+98 31 3260 0961
Email
sm.kermani@med.mui.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Keramni-Alghoraishi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Cardiology
Street address
Salman Farsi St., Shahid Chamran Heart Center
City
Isfahan
Province
Isfehan
Postal code
۸۱۵۸۳۸۸۹۹۴
Phone
+98 31 3260 0961
Email
sm.kermani@med.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Patients data (Unidentifiable), Study protocol, Consent form, Clinical report will be reported in final paper
When the data will become available and for how long
Approximately 1 year after article printing
To whom data/document is available
Academic researchers
Under which criteria data/document could be used
In order to complete further studies in this field
From where data/document is obtainable
Contact by email and phone with Dr. Mohammad Kermani-Alghoraishi sm.kermani@med.mui.ac.ir 0098 9133037414
What processes are involved for a request to access data/document
The data is available about 1 year after the publication of the article in the scope mentioned above in order to complete further studies.
Comments